REMARKS/ARGUMENTS

In a Decision on Appeal rendered by the Board of Patent Appeals and Interferences, new grounds of rejection under 37 C.F.R. §1.196(b) were offered. Appellant hereby responds to the new grounds of rejection.

Claims 1, 5 and 9 have been amended. Claims 6 and 8 have been canceled. New claims 19 and 20 are presented herewith. Reconsideration is respectfully requested.

Independent claim 13 stands rejected under 35 U.S.C. §102(b) as being anticipated by Kaehler et al., "Precoating Substrate and Surface Configuration Determine Adherence and Spreading of Seeded Endothelial Cells on Polytetrafluoroethylene Grafts" from *Journal of Vascular Surgery,* Vol. 9, No. 4; pp. 535-541; April 1989 (hereinafter "Kaehler").

The Board takes the position that Kaehler describes an implantable prosthesis including a body of PTFE having spaced apart nodes interconnected by fibrils with pores present between the nodes and the fibrils. The Board further takes the position that the body of the graft contains a biodegradable composition of natural origin within its pores. The Board finds that Kaehler meets each of the claim limitations of claim 13, specifically referring to the following passage of Kaehler contained on page 536 thereof:

> **Collagen types I and III.** A commercially available mixture of type I collagen (95%) and type III collagen (5%) was used (vitrogen 100; Collagen Corporation, Palo Alto, Calif.). After adding 12.5% 10x concentrated medium 199 (Flow Laboratories, McLean, Va.) and adjusting to pH 7.2 with 0.1N NaOH, the collagen solution was forced through the graft interstices. After the procedure was repeated three times excess collagen was removed from the graft lumen with a size 3 Fogarty catheter. After 60 minutes of incubation at 37° C the whole procedure was repeated twice. On the third occasion it was almost impossible to force the solution through the graft. Subsequently the graft was air dried for 20 hours at room temperature.

Contrary to the Board's determination, it is respectfully submitted that Kaehler does not anticipate claim 13 of the present invention.

Claim 13 recites as follows:

> An implantable prosthesis comprising a body of expanded polytetrafluoroethylene having a structure of spaced apart nodes interconnected by fibrils with pores present between said nodes and said fibrils; and a biodegradable composition of natural origin contained within said pores, <u>said biodegradable composition forming a precipitate that substantially fills said pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment</u>.

The present invention, as claimed is directed to an implantable prosthesis formed of ePTFE including node and fibril orientation. A biodegradable composition is retained within the pores

formed by the node and fibril structure. The biodegradable composition forms a precipitate that fills the pores at selected conditions of temperature and pH.

Turning now to Kaehler, specifically the paragraph noted by the Board, Kaehler employs a collagen solution used for precoating. The collagen solution is forced through the graft interstices. Once the collagen solution is forced into the interstices of the graft, it is air-dried at room temperature. As it relates to the claims of the present invention, Kaehler fails to disclose filling pores of an ePTFE graft with a biodegradable composition which forms a precipitate in the pores at selected conditions of temperature and pH.

Kaehler, instead, discloses a collagen solution which has been adjusted to a pH of 7.2. After such adjustment, collagen which is still in solution, is forced through the graft interstices. Once the solution itself is forced into the interstices, Kaehler does disclose air-drying the graft, however, there is no disclosure whatsoever of this air-drying step forming a collagen precipitate within the pores of the graft. Moreover, even if it were the case (which it is not) that a collagen precipitate is formed, there is no disclosure of using conditions of temperature and pH to form such a precipitate within the pores of the graft. The only disclosure in Kaehler of selecting conditions of pH is to adjust the pH at 7.2 at the solution stage of the collagen.

Contrary to the Board's position, Kaehler does not disclose, let alone teach, that the solidification or precipitation of collagen from a solution depends upon pH and temperature consideration. The fact that Kaehler cannot force additional solution through the graft at the end of a third procedure cannot be taken as a clear disclosure that collagen has precipitated at selected conditions of temperature and pH. Any attempt to read into Kaehler such an arrangement goes beyond the specific disclosure of the reference and, as such, fails under applicable law to be an anticipation of claim 13.

Since Kaehler discloses only adjusting the pH of the collagen solution and then filling the pores of the graft with the adjusted pH collagen, still in solution, Kaehler fails to disclose features of claim 13 of the present invention. As such, claim 13, and the claims which depend therefrom, are believed to be patentably distinct over Kaehler.

Claims 1-12 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. With respect to claim 1, the Board alleges that the manner in which claim 1 was amended during prosecution renders claim 1 at least ambiguous. The Board also states that claim 5 is indefinite and claim 8 appears to be redundant. Claims 1, 5, 7 and 9 have been amended and claims 6 and 8 have been canceled. Reconsideration is respectfully requested.

Claim 1 has been amended to clearly set forth that the claim is intended to be directed to a final product where an ePTFE substrate has its pores filled with a fluid which has been solidified. Furthermore, claim 1 has been specifically amended to recite that the biocompatible, biodegradable material is collagen.

The preferred method of preparing the prosthesis of the present invention is set forth in the present application at column 5, line 58 through column 6, line 15. It can be seen that a collagen solution having a pH within the range of about from 2 to 4 is prepared. The tubular prosthesis is then contacted with the collagen solution to allow for impregnation. The prosthesis is then treated with a chemical solution such as a buffered phosphate at a pH of about 7.4 to insolublize the collagen material in place. Claim 1 is clearly consistent with this preferred embodiment.

Since claim 1 has been amended, and the dependent claims have been conformed thereto, it is respectfully submitted that the Board's rejection under §112 is overcome. Reconsideration is respectfully requested.

Independent claim 1 stands rejected under 35 U.S.C. §103(a) as being obvious over Kaehler in view of U.S. Patent No. 5,197,977 to Hoffman et al. (hereinafter "Hoffman") and U.S. Patent No. 5,037,377 to Alonso. This determination is respectfully traversed.

Claim 1 is directed to an implantable member which has a solid precipitate of collagen formed in the pores. The solid precipitate is formed *in situ* from a collagen solution which has been pH adjusted to a pH of about 7.4.

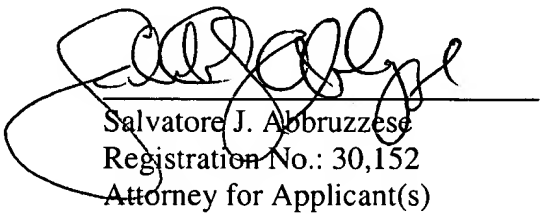
The Board acknowledges that Kaehler fails to show that the collagen material is insoluble at a pH of about 7.4. The Board uses the Hoffman and Alonso references to fill this deficiency stating that Hoffman and Alonso show that at the time of the present invention, workers of ordinary skill were aware of collagen coated synthetic implantable materials where collagen has been crosslinked. Notwithstanding the teaching of the secondary references, Kaehler, as noted above, fails to disclose collagen which has been pH adjusted at a pH of about 7.4 to form a solid precipitate *in situ*.

Kaehler notes that prior to impregnation, the collagen solution is adjusted to a pH of 7.2. The collagen solution is then forced into the pores of the PTFE graft and the graft it subsequently air-dried. Kaehler is silent on the ability to form a soluble solid precipitate *in situ* at a pH of

about 7.4. Therefore, notwithstanding the alleged teachings of Hoffman and Alonso, Kaehler, the basic reference, fails to form a solid insoluble precipitate of collagen at a pH of about 7.4 within the pores of a PTFE graft. It is respectfully submitted that the combination of Kaehler with Hoffman and Alonso fails to disclose, teach or suggest claim 1 of the present invention. Accordingly, claim 1 and the claims which depend therefrom are believed to be patentably distinct over the cited combination.

Should the Examiner have any questions or comments regarding this submission, the Examiner is invited to contact the undersigned attorney at the telephone number given below.

Respectfully submitted,



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